

OCT 17 2003

**Attachment 6**  
**510(k) Summary of Safety and Effectiveness**  
**September 15, 2003**

A. GENERAL INFORMATION

**Submitter's Name:** Radius Medical Technologies, Inc.  
**Address:** 15 Craig Road  
Acton, MA 01720  
**Contact Person:** Maureen A. Finlayson  
**Device Generic Name:** PTCA Guidewire  
**Device Trade Name:** Radius Cougar Wire  
**Classification Name:** Wire, Guide, Cardiovascular (74DQX)

B. INDICATIONS

The Modified **Radius Cougar Wire** is intended to facilitate the placement of balloon dilatation catheters during PTCA and/or PTA. The Modified **Radius Cougar Wires** are compatible with all currently approved and marketed PTCA balloon catheters which are labeled for use with an .014 guidewire.

C. DESCRIPTIVE CHARACTERISTICS

The Modified **Radius Cougar Wire** is constructed from a composite stainless steel and Nitinol core to which a coil is attached to the tapered distal section. The proximal section of the wire is coated with PTFE, and the distal coil portion of the wire is hydrophilic coated. The device is packaged in a protective hoop sealed into a Tyvek/mylar pouch, and is sterilized using ETO gas.

D. COMPARATIVE INFORMATION

The Modified **Radius Cougar Wire** is substantially equivalent to the currently marketed **Radius PTCA Guidewire (K970466)** and the **Radius Cougar Wire (K011287)**.

E. PERFORMANCE TESTING

The following in vitro performance tests were performed on the Modified **Radius Cougar Wire**:

1. Tensile Strength
2. Accelerated Age Testing
3. Coating Adherence/Integrity
4. Biocompatibility

**CONCLUSION:**

Based on the indications for use, technological characteristics, and safety and performance testing, the proposed modifications to the **Radius Cougar Wire** meets the minimum requirements that are considered adequate for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 17 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Radius Medical Technologies, Inc.  
c/o Ms. Debbie Iampietro  
7 Tiffany Trail  
Hopkinton, MA 01748

Re: K032899

Trade Name: Radius Cougar Wire  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Catheter Guide Wire  
Regulatory Class: Class II (two)  
Product Code: DQX  
Dated: September 15, 2003  
Received: September 18, 2003

Dear Ms. Iampietro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act


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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

  
for Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K032899

Device Name: Radius Cougar Wire

Indications For Use:

Radius Cougar Wire is intended for placement of balloon dilatation catheters during PTCA and/or PTA.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K032899

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_